Docket No.: 61755(51035)

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

John P. Maye et al.

Application No.: 09/520,004

Filed: March 6, 2000 Art Unit: 1794

ORGANISMS IN AN AQUEOUS PROCESS

For: PROCESS FOR CONTROLLING MICRO-

MEDIUM

Examiner: V. Stulii

Confirmation No.: 7731

APPEAL BRIEF

MS Appeal Brief - Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This brief is filed in accordance with 37 CFR 41.37. A Final Office Action was mailed from the USPTO on November 9, 2010, and a Notice of Appeal was filed on February 9, 2011. This Brief is timely filed.

BRIEF ON APPEAL FEE

Authorization to charge Deposit Account No. 04-1105 for \$270.00 is provided herewith to cover the appeal brief fee. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. 04-1105.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205.2:

I. Real Party In Interest

II Related Appeals and Interferences

III. Status of Claims

IV. Status of Amendments

V. Summary of Claimed Subject Matter

VI. Grounds of Rejection to be Reviewed on Appeal

VII. Argument
VIII. Claims
Appendix A Claims

Appendix B Evidence - Alcohol Distillers Handbook, pp. 172 and 182

Appendix C Evidence - Declaration from Chris Most

Appendix D Related Proceedings

REAL PARTY IN INTEREST

The real party in interest for this appeal is John I. Haas, Inc. The assignment of the invention to this corporation was recorded on December 15, 2006, at Reel/Frame 018638/0925.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 19 claims pending in the application.

B. Current Status of Claims

1. Claims canceled: 1, 19

2. Claims withdrawn from consideration but not canceled: none

3. Claims pending: 2-18, 20, 21

4. Claims allowed: none

5. Claims rejected: 2-18, 20, 21

C. Claims On Appeal

The claims on appeal are claims 2-18, 20, and 21

IV. STATUS OF AMENDMENTS

No amendments have been filed after issuance of the Final Office Action mailed on November 9, 2010.

A Pre-Appeal Brief Request for Review was filed on December 16, 2009. A Notice of Panel Decision from Pre-Appeal Brief Review issued on January 11, 2010, indicating that the rejections under 35 U.S.C. § 103(a) were overcome due to clear errors and/or omissions, and that prosecution was reopened. All of the rejections that were overcome included the rejections under 35 U.S.C. § 103(a) which had US 5,082,975 (herein referred to as "Todd") as the primary reference.

A Non-Final Office Action issued on March 30, 2010. Applicant subsequently filed an Amendment in Response to Non-Final Office Action on June 30, 2010. Supplemental amendments were filed on August 24, 2010, and September 2, 2010, in response to the Examiner interview that took place on July 15, 2010, between Supervisory Examiner Hendricks, Examiner Stulii, Sami Faour, and Jeffrey D. Hsi.

There are no unentered Amendments. A clean set of the claims on appeal is set forth in Appendix A.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claims 2 and 14 are pending and under examination in the application. Dependent claims 3-13, 15-18, 20 and 21 are also pending and under examination.

Independent claim 2 is directed to an improved process for inhibiting bacterial growth in an aqueous process medium comprising adding a hop acid, characterized in, that the process comprises:

- (a) dissolving the hop acid in an aqueous alkaline medium to form an aqueous alkaline hop acid solution;
- (b) combining the aqueous alkaline hop acid solution with yeast in a yeast growing tank wherein yeast growing is allowed to proceed under aerobic conditions to form a yeast/aqueous alkaline hop acid mixture,

(c) continuously adding an effective amount of the aqueous alkaline hop acid solution, pre fermentation, to a fermentation process medium in a fermentation tank, wherein the pH of the aqueous alkaline hop acid solution is higher than the pH of the aqueous process medium; and

(d) introducing the yeast/aqueous alkaline hop acid mixture of step (b) into the fermentation process medium of step (c) and allowing for fermentation to occur under anaerobic conditions.

Support for the claim can be found in the specification and claims as originally filed, e.g., original claims 1, 2 and 12; Figure 1; Figure 2; page 4, line 12 to page 5, line 2; and Example 5.

Independent claim 14 is directed to an improved process for inhibiting bacterial growth in a distillery comprising:

- (a) contacting a fermentable solution with an effective antibacterial amount of an isomerized alkaline hop acid solution or derivative thereof, to form an aqueous alkaline hop acid fermentable solution;
- (b) adding the aqueous alkaline hop acid fermentable solution of step (a) to a yeast growing tank comprising yeast, and allowing yeast growing to proceed under aerobic conditions;

and

(c) adding the contents in the yeast growing tank of step (b) to a fermentor tank, wherein fermentation is allowed to proceed under anaerobic conditions.

Support for the claim can be found in the specification and claims as originally filed, e.g., original claim 14, Figure 1; Figure 2; page 4, line 12 to page 5, line 6; page 11, lines 12-16; and Example 5.

Dependent claims 3-13, 15-18, 20 and 21 recite additional features of the claimed processes.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues on Appeal as to the rejection, or the grounds of rejection to be reviewed on appeal, are:

1. Whether claims 2-6, 8-11, 14, 15, 20 and 21 are obvious within the meaning of 35 USC §103(a) over Todd et al. (US 5,082,975) in view of Alcohol Distillers Handbook ("HANDBOOK"), Righelato et al. (Phil. Trans. R. Soc. Lond. B 290, (1980), 303-312) and Richards et al. (Plant Physiology, 1932, 7(1), 139-144).

- 2. Whether claims 7 and 16-18 are obvious within the meaning of 35 U.S.C. §103(a) over Todd et al. (US 5,082,975) in view of Alcohol Distillers Handbook ("HANDBOOK"), Righelato et al. (Phil. Trans. R. Soc. Lond. B 290, (1980), 303-312) and Richards et al. (Plant Physiology, 1932, 7(1), 139-144), and further in view of Simpson (J. Inst. Brew., 1987, 93, 405-406).
- 3. Whether claims 12 and 13 are obvious within the meaning of 35 U.S.C. §103 (a) over Todd et al. (US 5,082,975) in view of Alcohol Distillers Handbook ("HANDBOOK"), Righelato et al. (Phil. Trans. R. Soc. Lond. B 290, (1980), 303-312) and Richards et al. (Plant Physiology, 1932, 7(1), 139-144), Simpson (J. Inst. Brew., 1987, 93, 405-406), and further in view of US 4,002,863 (herein referred to as "Todd 2").
- 4. Whether the provisional rejection of claims 2-18, 20, and 21 under obviousness-type double patenting in view of claims 41 and 43-47 of copending US Patent Application No. 11/473,533 and in view of claims 34-40 of copending US Patent Application No. 10/361,976 should be withdrawn.

VII. ARGUMENT

As an initial matter, Appellants reiterate that subject to the Notice of Panel Decision from Pre-Appeal Brief Review, mailed on January 11, 2010, the following rejections under 35 U.S.C. § 103(a) were overcome due to clear errors and/or omissions:

- 1. Claims 2-6, 8-11, 14, 16, 20 and 21 were rejected under 35 USC 103(a) as obvious over US 5,082,975 (herein referred to as "Todd");
- 2. Claims 7 and 16-19 were rejected under 35 USC 103(a) as obvious over US 5,082,975 (Todd '975) in view of Simpson (J. Inst. Brew. 1987, vol. 93, pp. 405-406 (herein referred to as "Simpson")); and
- 3. Claims 12 and 13 were rejected under 35 USC 103(a) as obvious over US 5,082,975 (Todd) in view of Simpson, and further in view of US 4,002,683 (herein referred to as "Todd 2").

Thus, the rejections under 35 U.S.C. § 103(a), having Todd (US 5,082,975) as a primary reference, were previously overcome. However, prosecution was then reopened, and new grounds of rejection under 35 U.S.C. § 103(a) having Todd (US 5,082,975) as a primary reference were entered.

1. REJECTION OF CLAIMS 2-6, 8-11, 14, 15, 20 AND 21

Claims 2-6, 8-11, 14-15, and 20-21 are rejected as being unpatentable over Todd et al. (US 5,082,975) in view of Alcohol Distillers Handbook ("HANDBOOK"), Righelato et al. (Phil. Trans. R. Soc. Lond. B 290, (1980), 303-312) and Richards et al. (Plant Physiology, 1932, 7(1), 139-144), for the reasons as stated in the Office Action dated March 30, 2010. Appellants traverse.

Appellants note that the rejection in view of the primary reference (Todd) alone has been withdrawn, as stated above. Further, it is stated in the Office Action dated March 30, 2010, that "Todd is silent as to addition of hop acid solution to yeast in a yeast growing tank". Todd, in fact, provides absolutely no teaching of yeast propagation. As detailed below, Appellants submit that HANDBOOK, Righelato and Richards fail to remedy the deficiencies of Todd alone to render Appellants' claims obvious.

On page 6, first paragraph, lines 15-18 of the Office Action dated March 30, 2010, it is alleged that one of ordinary skill in the art would have been motivated to add hop acids solutions to the yeast growing tank, and then to transfer the mixture to the fermentation vessel. For support, the Examiner indicates that Todd discloses the addition of hexahydrolupulone to a yeast culture to inhibit the growth of Lactobacillus therein (Todd, column 3, lines 7-8). However, such a broadbrush interpretation fails to recognize fundamental differences in the Todd subject matter compared to Appellants' claimed subject matter.

First, the Todd teaching must inherently relate to anaerobic conditions, which are distinct and distinguishable from Appellants' claimed aerobic conditions in the yeast growing step. Todd's disclosure that treatment of a sugar solution inoculated with yeast,

with a hexahydrolupulone aqueous solution, did NOT inhibit fermentation (Todd, column 8, lines 3-4; emphasis added) further evidences that Todd's teachings relate only to anaerobic conditions, and not to a process including an aerobic yeast growing step, as presently claimed. Second, the disclosure at column 8, lines 3-4 of Todd does not teach or suggest an aqueous alkaline solution (unlike the presently claimed subject matter, which specifies use of an aqueous alkaline hop acid solution); rather, Todd discloses only a solution of hexahydrolupulone in water and glycerine. The use of glycerine in and of itself (to solubilize the hop acid) is an express indication that Todd teaches and prefers a formulation that is not an aqueous alkaline solution.

Moreover, this rejection ignores the full knowledge base that one of ordinary skill in the field would contemplate. Based on the contrary teaching of Simpson (J. Inst. Brew., 1987, 93, 405-406; cited in this Office Action), i.e., that hop resins are ineffective in controlling lactobacillus LA and LX (see, Simpson at p. 405, Figure 1, graphs titled "Lactobacillus LA" and "Lactobacillus LX" where the data delineated as the "•" line shows that hop resins do not kill (i.e., ca. 100% bacterial survival upon exposure to hop resins)), one of ordinary skill in the art would at least find the contrary teachings of Simpson and Todd to question any reasonable expectation of success for the Examiner's assertions, if not find an outright teaching away from Todd by Simpson of the Examiner's assertion that "one of ordinary skill in the art would have been motivated to add hop acids solutions to the yeast growing tank, and then to transfer the mixture to the fermentation vessel".

Each of the currently pending claims includes a method step wherein an aqueous alkaline hop acid solution and yeast are added into a yeast growing tank under aerobic conditions. Under such aerobic reaction conditions, those of ordinary skill in the art would undoubtedly realize that yeast will be growing and fermentation will be minimized due to the aerobic conditions. This is clearly distinct from the Todd reference which states that treatment of a 10% sugar solution, inoculated with yeast, with a 20% hexahydrolupulone solution, did NOT inhibit fermentation. Todd simply does not teach or suggest a separate step to grow yeast under aerobic conditions that minimizes fermentation as part of a process to inhibit bacterial growth in an aqueous process

medium. The Office Action dated March 30, 2010, even states that "Todd is silent as to addition of hop acid solution to yeast in a yeast growing tank".

Todd is directed towards a synthetic method of converting beta acids into reduced beta acids. Todd indicates that beta acids may be added to a yeast culture to inhibit bacterial growth (column 3, lines 7-8), and that the reduced beta acids may be used in the brewhouse (column 8, lines 5-10) which is an anaerobic system, and fails to suggest yeast propagation under aerobic conditions, as in the Appellants' claims. Additionally, Todd discloses that treatment of a sugar solution inoculated with yeast, with an alkaline beta hop acid solution in water, did NOT inhibit fermentation. This further evidences Todd's focus on anaerobic fermentation (and the desire of Todd to cause fermentation rather than propagate yeast biomass) and thus the failure of Todd to teach or suggest yeast propagation.

The Appellants' claims include a distinct and separate step wherein the aqueous alkaline solution of hop acid and yeast are added into a yeast growing tank under aerobic conditions, in order to allow the yeast to grow while avoiding/minimizing fermentation. The reason that fermentation is minimized at this point is that a buildup of ethanol resulting from fermentation will destroy the activity of the yeast. The motivation for yeast growing (in Appellants' claimed subject matter but not taught or suggested in Todd) is distinct and in fact contrary to the motivation for yeast use in Todd. Thus, the motivation of the yeast growing step is to maximize yeast growth in the presence of oxygen while at the same time minimizing fermentation, so that the yeast can be used later in the fermentation yessel.

In addition to the above, the subject matter of Todd actually is focused on a synthetic methodology for making hexahydrolupulone compounds. Aqueous alkaline solutions of hexahydrolupulone or beta hop acids happen to be provided in Examples 1 and 5 of Todd, but such alkaline solutions of hop acids are NOT used by Todd to inhibit bacterial growth. The aqueous alkaline solutions of hop acids presented by Todd are made for the purpose of purifying and/or extracting (i.e., separating from undesired catalyst poisons) the hop acids after a hydrogenation reaction, then acidified to give back more highly purified hop acids (in their acid form). Example 6 of Todd provides for

the use of hexahydrolupulone to inhibit bacterial growth using hexahydrolupulone dissolved in water and glycerine, wherein glycerine was added to solubilize the hexahydrolupulone (the alkaline form of hexahydrolupulone would not require the glycerine in an aqueous medium). Example 6 does NOT provide for an aqueous alkaline solution, nor for an aqueous alkaline solution of hop acid used to inhibit bacterial growth.

The only exemplification of the use of hop acids to inhibit bacteria in Todd is found in Example 6, but Example 6 simply does not use an aqueous alkaline solution of hop acids, and such a solution is not used <u>prior</u> to fermentation. Thus, Todd simply does not provide a teaching or suggestion of an aqueous alkaline solution of hop acid used to inhibit bacterial growth, and certainly not relating to pre-fermentation yeast treatment under aerobic conditions (as claimed by Appellants), and particularly in light of Simpson (teaching that hop resins are ineffective in controlling lactobacillus LA and LX), does not provide any teaching or suggestion with any reasonable expectation of success of a process having: (i) a distinct and separate step wherein an alkaline solution of hop acids and yeast are added into a yeast growing tank under aerobic conditions, in order to allow the yeast to grow while avoiding/minimizing fermentation, or (ii) two distinct steps wherein in one step, yeast is propagated under aerobic conditions in the presence of a hop acid solution, and then in another step, the yeast and hop acid solution is subjected to anaerobic fermentation conditions. Both (i) and (ii) are delineated elements of Appellants' claims.

It is alleged in the Office Action dated March 30, 2010, that HANDBOOK provides that hops extract is occasionally used with water for preparation of yeast mashes because it contains resins and is believed to inhibit the growth of microorganisms. HANDBOOK simply provides a general text of adding a hop resin extract to water to form a yeast mash. Appellants note that HANDBOOK provides for a hop resin extract, not an aqueous alkaline solution of hop acids.

As discussed supra, Simpson (J. Inst. Brew., 1987, 93, 405-406; cited in this Office Action) determined that hop resins are ineffective in controlling lactobacillus LA

and LX (see, Simpson at p. 405, Figure 1, graphs titled "Lactobacillus LA" and "Lactobacillus LX" where the data delineated as the "•" line shows that hop resins do not kill (i.e., ca. 100% bacterial survival upon exposure to hop resins)). Thus Simpson calls into question any assertion of a motivation to combine Todd and HANDBOOK and at a minimum evidences that there would be no reasonable expectation of success even if, arguendo, one of ordinary skill were motivated to combine Todd and HANDBOOK to attempt to arrive at Appellants' claims.

Appellants further submit that those of ordinary skill in the art were aware at the time of the instant invention that hop resin extracts would have been undesirable under the Appellants' method conditions due to the solubility problems of hop resin extracts and poor activity resulting from the solubility problems. Moreover, as discussed above, Simpson (teaching that hop resins are ineffective in controlling lactobacillus LA and LX) further counters the Examiner's assertions that HANDBOOK teaches a process having: (i) a distinct and separate step wherein an alkaline solution of hop acids and yeast are added into a yeast growing tank under aerobic conditions, in order to allow the yeast to grow while avoiding/minimizing fermentation, or (ii) two distinct steps wherein in one step, yeast is propagated under aerobic conditions in the presence of a hop acid solution, and then in another step, the yeast and hop acid solution is subjected to anaerobic fermentation conditions (again, both elements of Appellants' claims). Based on the data provided by Simpson, and the knowledge of the skilled artisan regarding the solubility and poor activity of hop resin extracts, hop resin extracts of HANDBOOK do not control bacteria. HANDBOOK does not teach or suggest anything that would rectify the deficiencies of Todd stated above.

It is stated in the Office Action dated March 30, 2010, that "Todd is silent as to addition of hop acid solution to yeast in a yeast growing tank" and it is then asserted in the Action that HANDBOOK at page 57 describes "preparation of yeast mash" and concluded from that that HANDBOOK provides the missing link between Todd and Appellants' claimed subject matter. Appellants traverse

HANDBOOK in fact <u>fails</u> to describe yeast propagation. The "yeast mash" described by HANDBOOK in fact *contains no yeast*. One of ordinary skill in the art

would understand and appreciate that "yeast mash" is the food or nutrient for yeast. Further, yeast mash does not contain yeast, and this is further evidenced by the definition of "yeast mash" that appears at page 182 of HANDBOOK (attached as Appendix B). Appellants submit that the paragraph of HANDBOOK cited in the Action, when read in context, does not describe yeast propagation and fails to describe Appellants' claimed subject matter. Moreover, when read in context, the cited paragraph of HANDBOOK describes "souring" without yeast being present, and the souring process is performed to encourage lactobacillus presence and function, precisely contrary to the functional outcome of Appellants' claimed subject matter.

The souring described in HANDBOOK is distinct from and in no way resembles Appellants claimed subject matter. Souring occurs with no yeast present and the cited hop resin extracts do not control bacterial proliferation. In fact, in souring, the medium is seeded with bacteria, then the medium is subjected to pasteurization to kill the bacteria. It is simply erroneous to extrapolate the teaching of HANDBOOK on souring to Appellants' claimed subject matter, and one of skill in the art would not be motivated to do so.

In the Office Action dated November 9, 2010, it is further alleged that HANDBOOK is relied upon as a "teaching of the fact that "[h]ops extract is occasionally used with water for preparation of yeast mashes because it contains resins and is believed to be inhibit growth of microorganisms". Such assertions ignore the vagaries of and gloss over the knowledge in the art that hop resin extracts in fact do not inhibit bacterial growth. There are a myriad of uses for yeast mash (including as explained above regarding "souring", for purposes contrary to that desired in Appellants' claims) and such a teaching fails to specifically teach or suggest Appellants methods having: (i) a distinct and separate step wherein an alkaline solution of hop acids and yeast are added into a yeast growing tank under aerobic conditions, in order to allow the yeast to grow while avoiding/minimizing fermentation, and (ii) two distinct steps wherein in one step, yeast is propagated under aerobic conditions in the presence of a hop acid solution, and then in another step, the yeast and hop acid solution is subjected to anaerobic fermentation conditions.

In the Office Action dated November 9, 2010, it states:

It is also noted that the term "yeast mash" suggests the presence of yeast. Even if the preliminary yeast mash does not contain yeast at the moment of addition of hop acids/extracts, it is intended for the so called "yeasting". i.e., addition of yeast. Thus, such "yeast mash" containing hop extracts/acids is contacted with yeast. (Office Action of November 9, 2010, at page 8).

Again, the Examiner essentially asserts that the presence of hop extract/acids in a yeast mash that ultimately "must" be introduced to yeast, equates to rendering obvious Appellants' methods. Appellants disagree. Such a conclusion is unwarranted, particularly when one of skill in the art reads the cited sections of HANDBOOK in their appropriate context, including p. 172 of HANDBOOK (i.e., the section on "yeasting", which discusses pasteurization prior to inoculation with yeast, but is devoid of any teaching regarding any other method of bacterial control; Appendix B). Because this is merely a teaching of yeast mash (again, where yeast is not necessarily present, coupled with the fact that there are a myriad of uses for yeast mash (including as explained above regarding "souring", for purposes contrary to that desired in Appellants' claims) and particularly in light of the contrary teachings of Simpson (i.e., the ineffectiveness of hop extracts to control lactobacillus), Todd and HANDBOOK, alone or in combination, do not provide any teaching or suggestion with any reasonable expectation of success of Appellants' claimed methods.

No combination of Todd and HANDBOOK provides any teaching or suggestion of a distinct and separate step wherein an alkaline solution of hop acids and yeast are added into a yeast growing tank under aerobic conditions, in order to allow the yeast to grow while avoiding/minimizing fermentation. Additionally, no combination of Todd and HANDBOOK teaches or suggests two distinct steps wherein in one step, yeast is propagated under aerobic conditions in the presence of a hop acid solution, and then in another step, the yeast and hop acid solution is subjected to anaerobic fermentation conditions.

It is alleged that Righelato describes "fermentation, the anaerobic catabolism of carbohydrates, proceeds by the oxidation of sugars to pyruvic acid..." It is further alleged that Richards discloses consumption of oxygen during yeast growth. The Office Action then states that one of ordinary skill in the art would have been motivated by

Todd to employ conventional conditions for alcohol fermentation and yeast growth such as aerobic conditions for yeast growth and anaerobic conditions for fermentation.

Appellants contend that Righelato simply provides a general text of fermentation using various sugar sources. There is nothing in Righelato that teaches or suggests a hop acid or an aqueous alkaline solution of hop acids. Righelato does not teach or suggest anything that would rectify the deficiencies of Todd stated above. In fact, Appellants submit that the combination of Todd and Righelato teaches nothing more than what is already disclosed in Todd. No combination of Todd and Righelato provides any teaching or suggestion of a distinct and separate step wherein an alkaline solution of hop acids and yeast are added into a yeast growing tank under aerobic conditions, in order to allow the yeast to grow while avoiding/minimizing fermentation. Additionally, no combination of Todd and Righelato teaches or suggests two distinct steps wherein in one step, yeast is propagated under aerobic conditions in the presence of a hop acid solution, and then in another step, the yeast and hop acid solution is subjected to anaerobic fermentation conditions.

Richards is directed towards measuring the amount of oxygen consumption and carbon dioxide production by yeast under aerobic conditions. There is nothing in Richards that teaches or suggests a hop acid or an aqueous alkaline solution of hop acids. Further, there is nothing in Richards that teaches or suggests that the grown yeast is added to a process medium, regardless of whether or not hop acids are included. Richards does not teach or suggest anything that would rectify the deficiencies of Todd stated above. No combination of Todd and Richards provides any teaching or suggestion of a distinct and separate step wherein an alkaline solution of hop acids and yeast are added into a yeast growing tank under aerobic conditions, in order to allow the yeast to grow while avoiding/minimizing fermentation. Additionally, no combination of Todd and Richards teaches or suggests two distinct steps wherein in one step, yeast is propagated under aerobic conditions in the presence of a hop acid solution, and then in another step, the yeast and hop acid solution is subjected to anaerobic fermentation conditions.

For the reasons stated above, Appellants submit that Todd in combination with any or all of HANDBOOK, Righelato, or Richards, does not provide any motivation, reasonable expectation of success, or provide a disclosure of all of the elements of the Appellants' claims as pending. The Office Action has failed to make out a prima facie case of obviousness of the present claims. Appellants submit that the rejection is overcome and respectfully request withdrawal of the rejection.

1A. SURPRISING ADVANTAGES OF THE INVENTION

Even if the Office Action had made out a *prima facie* case of obviousness of the present claims (which Appellants strongly dispute, as discussed above), any such *prima facie* case is rebutted by the unexpected and surprising results of the claimed methods, as previously described in a declaration under 37 CFR 1.132, executed by Chris Most and filed on September 19, 2008, and filed with the Pre-Appeal Brief Remarks on December 16, 2009. The declaration is attached as Appendix C.

Mr. Most (who is not an applicant in this matter) supervised or conducted experiments to examine the effect of hop acids in fuel ethanol production. Mr. Most indicates that it is his expert opinion that one of ordinary skill in this field would not have expected the use of hops acids in the manner described in the pending claims to have any appreciable effects on fuel ethanol production. Mr. Most then details his experience comparing production runs wherein hop acids were administered pre-fermentation in a yeast propagation vessel, compared to production runs without the hop acids, and describes numerous unexpectedly improved properties. The declaration of Mr. Most must be accorded due consideration. See, *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992) (office personnel should consider declarations from those skilled in the art praising the claimed invention); MPEP 2145 (rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties).

Mr. Most also indicated that the addition of aqueous alkaline solutions of hop acids, administered pre-fermentation during the production of fuel ethanol in processes

conducted by him or under his supervision, provided numerous surprising and unexpected benefits in the fuel ethanol production process including healthier yeast counts, increased throughput capacity, improved maintenance of acceptable alcohol levels, and increased "backset" (virtually double, from 10% to 19%). Specifically, the Most Declaration states that increased "backset" is particularly useful in decreasing cost and starting materials through water recycling, greater pollution control, reduction of liquid residue required, and reduction in acidity. Moreover, this advantage allowed the plant to lower sulfuric acid consumption, which allowed the plant to meet sulfur content specifications. In all, Appellants' claimed process provided numerous unexpected commercial and environmental advantages to the fuel ethanol production plant.

None of the aforementioned advantages is taught or suggested by Todd, whether alone or in combination with any of the references cited in the Office Action. Thus even, *arguendo*, were a *prima facie* case of obviousness established based on Todd alone or in combination with any of the references cited in the Action (which Appellants do not believe has been established), the Most Declaration provides a showing of surprising and unexpected benefits (both in variety and level) of Appellants' claimed subject matter that is more than sufficient to overcome the rejection.

2. REJECTION OF CLAIMS 7 AND 16-18

Claims 7 and 16-18 are rejected as being unpatentable over Todd et al. (US 5,082,975) in view of Alcohol Distillers Handbook ("HANDBOOK"), Righelato et al. (Phil. Trans. R. Soc. Lond. B 290, (1980), 303-312) and Richards et al. (Plant Physiology, 1932, 7(1), 139-144), and further in view of Simpson (J. Inst. Brew., 1987, 93, 405-406), for the reasons as stated in the Office Action dated March 30, 2010. It is alleged that Simpson discloses aqueous alkaline solutions of isomerized hop acids in an example using ISOHOPCO₂N.

As indicated previously, the rejection of claims 7 and 16-19 over the combination of Todd and Simpson, has been overcome to due clear errors and/or omissions (see Notice of Panel Decision from Pre-Appeal Brief Review, mailed on January 11, 2010). The discussion, *supra*, regarding HANDBOOK, Righelato, and

Richards, demonstrates that any or all of the three references in combination with Todd, fail to teach or suggest the methods of the pending claims. For at least the foregoing reasons, the rejection is obviated and withdrawal of the rejection is requested.

3. REJECTION OF CLAIMS 12 AND 13

Claims 12 and 13 are rejected as being unpatentable over Todd et al. (US 5,082,975) in view of Alcohol Distillers Handbook ("HANDBOOK"), Righelato et al. (Phil. Trans. R. Soc. Lond. B 290, (1980), 303-312) and Richards et al. (Plant Physiology, 1932, 7(1), 139-144), and further in view of Simpson (J. Inst. Brew., 1987, 93, 405-406), and further in view of US 4,002,863 (herein referred to as "Todd 2"), for the same reasons as stated in the Office Action dated March 30, 2010.

As indicated previously, the rejection of claims 12 and 13 over the combination of Todd and Simpson in view of Todd 2, has been overcome to due clear errors and/or omissions (see Notice of Panel Decision from Pre-Appeal Brief Review, mailed on January 11, 2010). The discussion, *supra*, regarding HANDBOOK, Righelato, and Richards, demonstrates that any or all of the three references in combination with Todd, fail to provide for the methods of the claimed invention. For at least the foregoing reasons, the rejection is obviated and withdrawal of the rejection is requested.

4. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS

Claims 2-18, 20, and 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41 and 43-47 of co-pending Application No. 11/473,533, and claims 34-40 of co-pending Application No. 10/361,976. Appellants have addressed all other rejections and therefore, pursuant to MPEP 1490(V)(D), as the provisional obviousness type double patenting rejection is the only rejection remaining, and applications 11/473,533 and 10/361,976 are still pending applications, Appellants request withdrawal of the rejections and allowance of this application.

VII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A include the amendments filed by the Applicant on September 2, 2010.

CONCLUSION

For at least the foregoing reasons, Appellants contend that the rejections of record should be withdrawn, and that the present application is in condition for allowance. Early and favorable consideration of the application is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 61755 (51035).

Dated: March 9, 2011 Respectfully submitted,

By: /Dwight D. Kim/
Jeffrey D. Hsi, Registration No.: 40,024
Dwight D. Kim, Registration No.: 57,665
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 239-0100
Attorneys/Agents For Appellants
Customer Number 21874

APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/520,004

Claim 1 (canceled)

Claim 2 (Previously presented): An improved process for inhibiting bacterial growth in an aqueous process medium comprising adding a hop acid, characterized in, that the process comprises:

- (a) dissolving the hop acid in an aqueous alkaline medium to form an aqueous alkaline hop acid solution;
- (b) combining the aqueous alkaline hop acid solution with yeast in a yeast growing tank wherein yeast growing is allowed to proceed under aerobic conditions to form a yeast/aqueous alkaline hop acid mixture,
- (c) continuously adding an effective amount of the aqueous alkaline hop acid solution, pre fermentation, to a fermentation process medium in a fermentation tank, wherein the pH of the aqueous alkaline hop acid solution is higher than the pH of the aqueous process medium; and
- (d) introducing the yeast/aqueous alkaline hop acid mixture of step (b) into the fermentation process medium of step (c) and allowing for fermentation to occur under anaerobic conditions.

Claim 3 (Previously presented): A process according to claim 2, wherein the aqueous alkaline hop acid solution contains from about 2 to about 40 wt. % of hop acid.

Claim 4 (Previously presented): A process according to claim 2, wherein the pH of the aqueous alkaline hop acid solution ranges from about 7.5 to about 13.0.

Claim 5 (Previously presented): A process according to claim 2, wherein the hop acid is a natural hop acid or derivative thereof; an isomerized hop acid or derivative thereof; or mixtures thereof.

Claim 6 (Original): A process according to claim 5, wherein the natural hop acid or derivative thereof is alpha acid, beta acid, tetrahydroalpha acid, hexahydrobeta acid, or mixtures thereof.

Claim 7 (Original): A process according to claim 5, wherein the isomerized hop acid or derivative thereof is isoalpha acid, rhoisoalpha acid, hexahydroisoalpha acid, or mixtures thereof.

Claim 8 (Previously presented): A process according to claim 2, wherein the aqueous alkaline medium comprises from about 1 to about 5 wt. % of potassium hydroxide, sodium hydroxide or mixtures of potassium hydroxide and sodium hydroxide.

Claim 9 (Previously presented): A process according to claim 2, wherein the temperature of the aqueous process medium is lower than 100° C.

Claim 10 (Previously presented): A process according to claim 2, wherein the concentrations of the hop acid within the aqueous process medium is in the range of 0.1 - 50 ppm.

Claim 11 (Previously presented): A process according to claim 2, wherein the aqueous process medium is a process medium in a yeast production process.

Claim 12 (Previously presented): A process according to claim 2, wherein the aqueous alkaline hop acid solution is prepared according to the following process:

- a. heating an aqueous medium;
- adding a hop acid to the heated aqueous medium of step (a) to form a solution wherein a final concentration of the hop acid is within a predefined range of concentration;
- adding an alkali metal hydroxide to a second aqueous medium to obtain a solution having a pre-defined pH;
- mixing the alkaline medium from step (c) with the hop acid aqueous medium from step (b);

e. keeping the mixture from step (d) in a temperature range used in step (a) within a pre-defined time period;

- f. separating a solution of hop acid from the mixture of step (e); and
- g. cooling the solution of hop acid from step (f) to a temperature below about 20° C.

Claim 13 (Previously presented): A process according to claim 12, wherein the aqueous alkaline hop acid solution is cooled to a temperature below 10° C.

Claim 14 (Previously presented): An improved process for inhibiting bacterial growth in a distillery comprising:

- (a) contacting a fermentable solution with an effective antibacterial amount of an isomerized alkaline hop acid solution or derivative thereof, to form an aqueous alkaline hop acid fermentable solution;
- (b) adding the aqueous alkaline hop acid fermentable solution of step (a) to a yeast growing tank comprising yeast, and allowing yeast growing to proceed under aerobic conditions;

and

(c) adding the contents in the yeast growing tank of step (b) to a fermentor tank, wherein fermentation is allowed to proceed under anaerobic conditions.

Claim 15 (Original): A process according to claim 14 wherein, the isomerized hop acid or derivative thereof is isoalpha acid, rhoisoalpha acid, tetrahydroisoalpha acid, hexahydroisoalpha acid, or mixtures thereof.

Claim 16 (Previously presented): A process according to claim 14 wherein, the fermentable solution is stored as a concentrate and diluted with water prior to the addition of the isomerized alkaline hop acid in step (a).

Claim 17 (Previously presented): A process according to claim 16 wherein, the pH of the isomerized alkaline hop acid solution is greater than the pH of the fermentable solution.

Claim 18 (Previously presented): A process according to claim 14 wherein, the concentration of isomerized alkaline hop acid or derivative thereof in the alkaline hop acid fermentable solution ranges from about 1 to about 20 ppm.

Claim 19 (Canceled).

Claim 20 (Previously presented) A process according to claim 14, wherein the addition of the alkaline hop acid fermentable solution in step (b) occurs at a temperature of less than about 30° C.

Claim 21 (Previously presented): A process according to claim 2, wherein the temperature of the aqueous process medium is lower than 30° C.

APPENDIX B

ALCOHOL DISTILLERS HANDBOOK (HANDBOOK), pp. 172 AND 182

F. for a period of 10 minutes and is then pumped through the coolers to the fermenters.

FERMENTATION

ment-such as mash coolers, pumps, and beer stills-determine The alcohol tolerance of the yeast and the mechanical limits of the equip-Mash is usually fermented as 34-48 gallon beer. mash concentration.

pH of the set fermenter is adjusted with 15-30% stillage to 4.6.4.8, to reduce the possibility of contamination. Too low a maximum temperature does not exceed 89-90° F. during the fermenters are equipped with cooling coils or an external heat Setting temperature (68-75° F.) is adjusted so that the course of fermentation. The weather and the size of fermenexchanger, they may be set at a temperature as high as 87° F. ters determine the selection of the setting temperature. setting pH interferes with the secondary conversion.

YEASTING

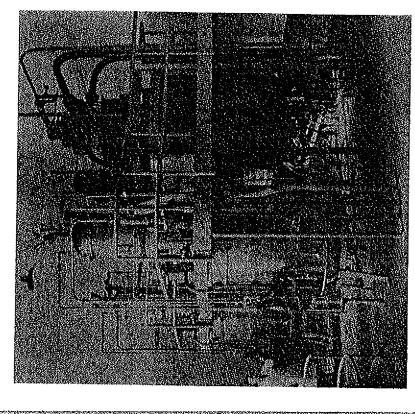
The following procedure is used frequently: water is drawn at a ratio of 12-13 gallons per bushel, and malt and wheat (or and 152° F. The mash is held at each of these temperatures rye) are added. The mash is heated by stages to 130°, 145°, for a period of 20-30 minutes.

desired pH (3.9), a small quantity of mash is withdrawn F. and is stocked with a lactic culture. The temperature of 126-128° F. is maintained until the mash is sufficiently sour. aseptically into a sterile container and is stored at room tem-After distribution in yeast tubs, the mash is cooled to 128° perature as lactic inoculum for the next batch of mash. Frequent agitation insures a uniform temperature.

The mash is heated to 140° F. in order to arrest the souring process. As needed, the mash is pasteurized by being heated

APPENDIX

balling of about 9 to 11. Yeast should be ready for the fer-The pasteurized mash The yeast is then cooled as required, in order to obtain a final menter after an incubation period of approximately 16 to 22 is cooled to approximately 75° F. and is inoculated with yeast. Temperature of the working yeast is allowed to rise to 84° F. to 180° F. and a period of 30 minutes. hours. Pasteurized sour mash withdrawn from a yeast tub may be used as medium for a dona.



Pure culture machines for yeast and Lactobacillus Delbrücki (Courtesy of Hiram Walker & Sons, Inc.)

been decided whether to classify it with corn or with the small grains.

Sour:

Acidified mash. To sour means to acidify mash with lactic acid bacteria.

Sour yeast:

Yeast grown in acidified mash.

Stillage:

De-alcoholized beer, i.e., residue left after distillation.

Thin Stillage:

Liquid portion of screened stillage.

Sweet yeast:

Yeast grown in un-acidified mash.

Tails:

Alcoholic distillate containing a high percentage of fusel oil.

Yeast:

Mash containing yeast cells, used for inoculation of main mash in fermenters.

Yeast Mash:

Mash prepared for the cultivation of yeast before being transferred to the main mash.

APPENDIX C

Declaration under 37 C.F.R. 1.132 executed by Chris Most, originally filed on September 19, 2008, and refiled with the Pre-Appeal Brief Request on December 16, 2009.

RECEIVED CENTRAL FAX CENTER

SEP 1 9 2008

Docket No. 61755(51035)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

J.P. Maye

Serial No.:

09/520,004

Filed:

February 10, 2003

For:

PROCESS FOR CONTROLLING MICRO-ORGANISMS IN AN AQUEOUS

PROCESS MEDIUM

Examiner:

Vera Stulli

Art Unit:

1617

Mail Stop: Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450.

Sir:

DECLARATION UNDER 37 C.E.R. 1.132

- I, Chris Most, a citizen of the United States of America, hereby declare as follows:
- 1. I am Production Manager at Nebraska Energy LLC, 1205 South O Road, Aurora, NE 68818-5304.
- 2. I understand that this declaration is submitted in support of pursuing a U.S. patent on the subject matter described and claimed in the patent application U.S.S.N. 09/520,004, filed on February 10, 2003 and otherwise identified above.

- 3. I understand that the claims relating to use of hop acids in processes for producing ethanol in the above-identified application are asserted by the Examiner to be obvious in view of the art documents cited in the Office Action dated March 19, 2008 and that this declaration is being submitted to support a response rebutting that assertion.
- 4. Based on my knowledge and expertise as a practitioner in this field and based on my experience in the field, it is my expert opinion that prior to conducting any experiments on the effect of administration of hop acids in fuel ethanol production, one of ordinary skill in this field would not have expected the use of hop acids in the manner claimed in the above-identified application to have any appreciable effects on fuel ethanol production.
- 5. The following experiments or treatments were conducted by me or under my supervision, to examine the effect of administration of hop acids in fuel ethanol production.
- We performed fermentation processes to produce fuel ethanol wherein hop acids were not used in any form during processing.
- 7. We then performed fermentation processes to produce fuel ethanol essentially as described in Section 6 above wherein the only change was that hop acids (e.g., isoalpha acids in alkaline solution form) were administered pre-fermentation during the process in the yeast propagation vessel.
- 8. These results indicate that administration of hop acids in the form and manner described in Section 7 above relative to Section 6 above (i.e., control) provided the following surprising and unexpected benefits: (i) healthier yeast counts along the fermentation train, process, especially at the back end, which led to better glucose utilization and higher alcohol numbers; (ii) increase throughput capacity; (iii) improved maintenance of acceptable alcohol levels during all plant upset events

NO. 9652 P. 19

occurring during treatments; (iv) increased "backset" from about 10% to about 19%, which enabled the plant to lower sulfuric acid consumption needed for pH adjustment of the fermenters which in turn allowed the plant to meet sulfur content specifications in the ethanol produced and reduced the amounts of fresh water required in the front end of the process. "Backset" (aka recycled thin stillage) is a significant production advantage because: (a) it allows for greater water recycling, which reduces costs associated with the need to continuously introduce new fresh water to the process; (b) it is a source of nutrients for the process; (c) it results in greater pollution control due to reduced effluent production and reduced biological oxygen demand (BOD) to the environment; (d) it reduces the liquid residue required to be evaporated; (e) it lowers the acidity of the mash medium thus reducing the need for additional amounts of sulfuric acid in the process (which is crucial for meeting sulfur specifications in the final fuel ethanol product). In summary, these advantages observed in the processes using hop acids as described above result in a significantly improved and more efficient process for ethanol production. The observed specific advantages delineated above as well as the improved overall process were unexpected.

9. I, the undersigned Chris Most, further declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 101 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the above identified application or any patent issuing thereon.

Reduction Manager LLC

APPENDIX D

There are no related proceedings with respect to section II. above, hence copies of decisions in related proceedings are not provided.

Docket No. TRANSMITTAL OF APPEAL BRIEF 61755(51035) In re Application of: John P. Maye et al. Application No. Group Art Unit Filing Date Examiner 1794 09/520,004-Conf. #7731 March 6, 2000 V. Stulii PROCESS FOR CONTROLLING MICRO-ORGANISMS IN AN AQUEOUS PROCESS Invention: **MEDIUM** TO THE COMMISSIONER OF PATENTS: Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal February 9, 2011 . filed: The fee for filing this Appeal Brief is \$270.00 Large Entity x Small Entity A petition for extension of time is also enclosed. The fee for the extension of time is ______ . A check in the amount of is enclosed. X Charge the amount of the fee to Deposit Account No. 04-1105 . Payment by credit card. Form PTO-2038 is attached. X The Director is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 04-1105 This sheet is submitted in duplicate. /Dwight D. Kim, Ph.D./ Dated: March 9, 2011 Dwight D. Kim, Ph.D. Attorney Reg. No.: 57,665 EDWARDS ANGELL PALMER & DODGE LLP P.O. Box 55874 Boston, Massachusetts 02205 (617) 517-5588